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PRECLINICAL RESEARCH

# Leadless Dual-Chamber Pacing

## A Novel Communication Method for Wireless Pacemaker Synchronization

Lukas Bereuter, MSc,[a,b] Mirco Gysin, MSc,[b] Thomas Kueffer, MSc,[a,b] Martin Kucera, MSc,[c] Thomas Niederhauser, PhD,[c] Jürg Fuhrer, MD,[a] Paul Heinisch, MD,[d] Adrian Zurbuchen, PhD,[e] Dominik Obrist, PhD,[b] Hildegard Tanner, MD,[a] Andreas Haeberlin, MD, PhD[a,b]

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**CME/MOC/ECME Objective for This Article:** Upon completion of this activity, the learner should be able to: 1) describe the current clinical use of leadless single chamber pacemakers in various patient populations; 2) identify the potential role of a leadless dual chamber as compared with the currently available, conventional leadless single chamber pacemaker; and 3) examine the concept of intra-body communication to preserve synchrony and act as an energy-efficient mode of wireless communication.

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From the [a]Department of Cardiology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland; [b]ARTORG Center for Biomedical Engineering Research, University of Bern, Bern, Switzerland; [c]Institute for Human Centered Engineering, Bern University of Applied Sciences, Biel, Switzerland; [d]Department of Cardiovascular Surgery, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland; and the [e]Electrical Engineering and Computer Science Department, University of Michigan, Ann Arbor, Michigan. This study was supported by the research funds of the Department of Cardiology, Bern University Hospital,

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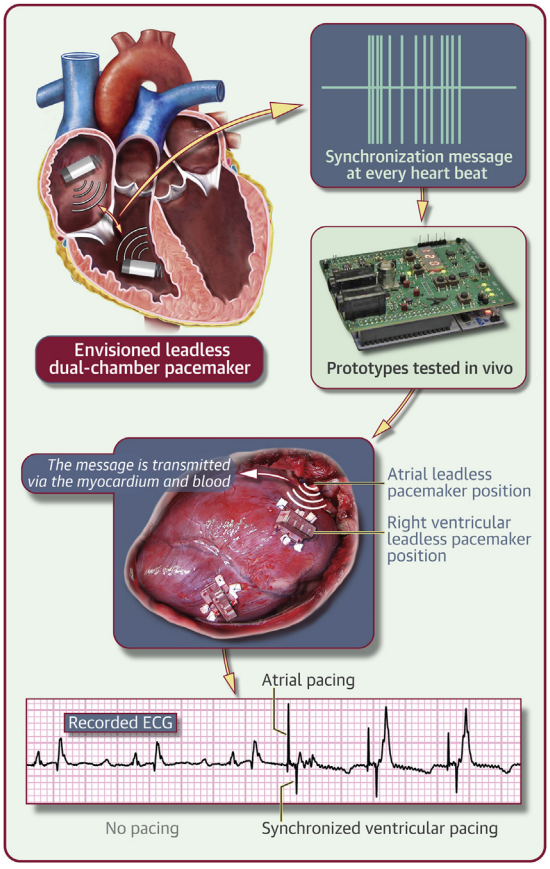
**VISUAL ABSTRACT**




Bereuter, L. et al. J Am Coll Cardiol Basic Trans Science. 2018;3(6):813–23.

**HIGHLIGHTS**

- **The new leadless pacemakers overcome important limitations of conventional devices but only provide single-chamber pacing capability.**
- **The presented concept involves 2 leadless pacemakers that communicate wirelessly with each other and thus enable synchronized leadless dual-chamber pacing.**
- **A novel technology is presented for pacemaker communication, using the myocardium and blood as the transmission medium. Optimal communication parameters were assessed in vivo and in vitro, and various features having an influence on signal transmission have been identified.**
- **A leadless dual-chamber pacemaker prototype was developed and successfully tested in vivo.**
- **The presented technique has shown to be a promising and energy-efficient wireless communication method for leadless dual-chamber pacemakers.**

the Swiss Heart Foundation, and the Swiss Foundation for Pacemaker and Electrophysiology. All authors have reported that they have no relationships relevant to the contents of this paper to disclose.
All authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the *JACC: Basic to Translational Science* author instructions page.

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**SUMMARY**

Contemporary leadless pacemakers only feature single-chamber pacing capability. This study presents a prototype of a leadless dual-chamber pacemaker. Highly energy-efficient intrabody communication was implemented for wireless pacemaker synchronization. Optimal communication parameters were obtained by in vivo and ex vivo measurements in the heart and blood. The prototype successfully performed dual-chamber pacing in vivo. The presented wireless communication method may in the future also enable leadless cardiac resynchronization therapy. (J Am Coll Cardiol Basic Trans Science 2018;3:813–23) © 2018 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

**ABBREVIATIONS AND ACRONYMS**

**AV** = atrioventricular
**ECG** = electrocardiogram
**LV** = left ventricle
**PM** = pacemaker
**RA** = right atrium
**RV** = right ventricle

Today, >1 million cardiac pacemakers (PMs) are implanted per year (1), the majority of which are conventional PMs. These devices consist of a subcutaneously implanted generator and pacing leads. However, conventional PM systems suffer from limitations: ~10% of PM patients experience complications, which are mostly related to the pacing leads or involve pocket-related complications (2,3). To overcome these limitations, leadless single-chamber PMs have been introduced. These devices are implanted inside the right ventricle using dedicated delivery catheters. In addition to offering a cosmetic benefit, the leadless design and the lack of a surgically created subcutaneous pocket eliminate major drawbacks. To date, 2 leadless PMs are commercially available: Micra (Medtronic, Minneapolis, Minnesota) and Nanostim (St. Jude Medical, St. Paul, Minnesota) (4–8). However, these devices have the significant limitation of performing single-chamber ventricular pacing only. Therefore, present leadless PMs are not well suited for the majority of patients in whom a dual-chamber system or cardiac resynchronization therapy is preferred due to medical reasons (9). Communication between different pacing sites is also key to reducing right ventricular pacing. Hence, dual-chamber pacing systems that profit from the advantages of leadless PMs are highly desirable.

The concept proposed in the present study involves multiple implanted leadless PMs that jointly act as a leadless dual-chamber PM system (**Figure 1**). To preserve synchrony, these devices must communicate wirelessly with each other. A typical communication scenario in a leadless dual-chamber PM system could work as follows: the atrial PM stimulates the right atrium (RA) and immediately sends a synchronization message to the ventricular PM that comprises information such as the atrioventricular pacing delay. This message is received almost instantly by the ventricular PM, which reacts accordingly within the same heart cycle. Therefore, the connection has to be established in a very short time although the amount of transferred data is very small. Furthermore, leadless PMs consume only 5 to 10 μW of power (according to device manufacturer's reference manuals), which is important due to the highly restricted battery volume. Therefore, the communication must be very energy efficient and should not significantly reduce the lifetime of a PM. Inside the body, these requirements can typically not be met with wireless data communications based on radiofrequency telemetry and inductive coupling (as used by conventional cardiac implantable devices) (10,11). In contrast, galvanic coupled intrabody communication (12) is a promising approach for wireless data transfer between implanted devices. It uses the tissue as a transmission medium for electrical signals: the data from one device are modulated and applied as a small alternating current signal to the tissue via electrodes. This current will propagate in the tissue and can be registered almost simultaneously by another device.

Galvanic coupled intrabody communication has mainly been investigated as a wireless communication method for on-body biomedical sensor networks (10,12). To characterize the human body as a transmission medium for electrical current, tissue properties and geometrical alignment influences have been investigated. However, most studies focus on transmission between body extremities using surface electrodes (13–15). For the proposed communication between leadless PMs, the dominant transmission medium is the myocardium/blood, and the communication electrodes are preferably the PM electrodes.

In the present study, the heart's electrical signal transmission characteristics were assessed to develop a prototype of a leadless dual-chamber PM using intrabody communication for device synchronization. The PM underwent in vivo testing to investigate the method's acute safety and ability to allow multisite pacing.

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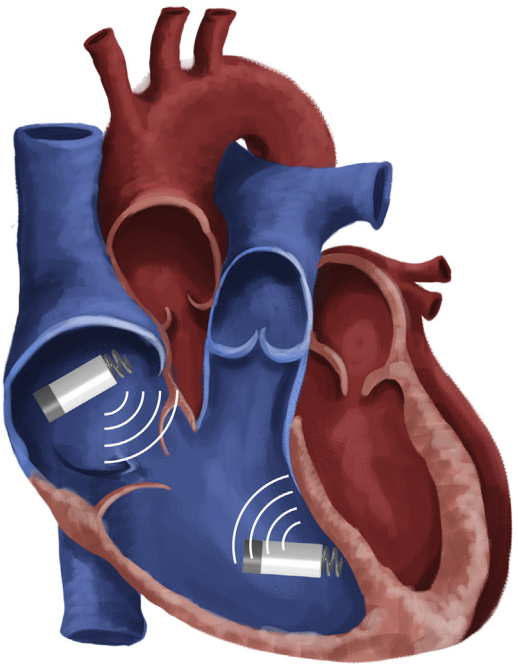
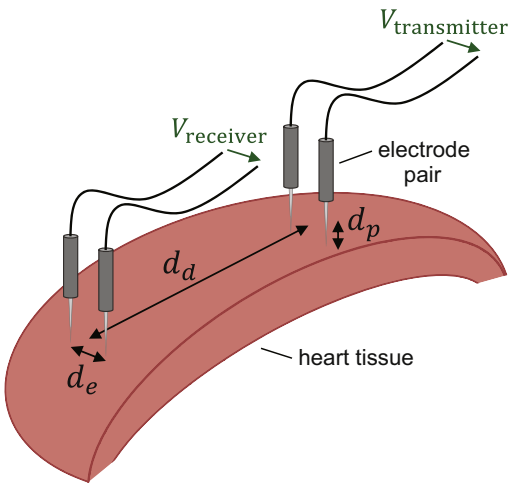
**FIGURE 1** Leadless Dual-Chamber Pacemaker



Leadless pacemakers are implanted in the right atrium and the right ventricle. To synchronize, the devices communicate wirelessly with each other.

**FIGURE 2** Schematic Setup of Ex Vivo and In Vivo Measurements and Representation of Introduced Parameters




Two electrode pairs penetrate the myocardium with defined geometrical relations: electrode distance ($d_e$), device distance ($d_d$), and penetration depth ($d_p$). The signal attenuation in the tissue is defined by the relation of the voltages $V_{transmitter}$ and $V_{receiver}$.

## METHODS

**IMPEDANCE AND TRANSFER FUNCTION MEASUREMENTS.** To build the wireless dual-chamber PM, we first investigated the key characteristics for intrabody communication inside the heart. The impedance between the communication electrodes $Z_e$ is a first key parameter to be characterized. It is mainly defined by the surrounding tissue, the electrode distance ($d_e$), and the electrode penetration depth ($d_p$) (Figure 2). Ultimately, the impedance affects the transmitted power during communication. The second key parameter is the transfer function ($H(f)$), which describes the frequency-dependent attenuation of the electrical signal in the tissue. It is a relation between the voltage ($V_{transmitter}$), which is applied by the transmitting electrode pair, and the voltage $V_{receiver}$, measured by the receiving electrode pair at a different location:

$$H(f) = 20 \cdot \log_{10}\left(\frac{V_{receiver}}{V_{transmitter}}\right) \qquad \text{(Equation 1)}$$

The specific range of impedances and the transfer functions of myocardial tissue were determined with measurements on porcine hearts. To obtain realistic results, measurements were performed either ex vivo on beating hearts (Langendorff technique [16]) or in vivo on 60-kg domestic pigs. During the in vivo measurement, the pig was under inhalation anesthesia and placed in a recumbent position. Before the experiment, a bolus of 150 mg of amiodarone and 5,000 U of heparin were administered intravenously. After performing a sternotomy, electrode fixation plates were sutured epicardially on the RA and the right ventricle (RV). The electrodes were stuck into the myocardium through the electrode fixation plates with different distances. Medical-grade stainless steel needles with a maximal diameter of 0.55 mm (8140-8 Pc, Sutranox, Unimed S.A., Lausanne, Switzerland) were used as electrodes.

Impedance was measured with an impedance spectroscope (HF2IS in combination with HF2TA, Zurich Instruments, Zurich, Switzerland). To acquire the transfer function, a frequency sweep of a sinusoidal voltage (1 kHz to 1 MHz) was generated with a signal generator (HF2IS, Zurich Instruments). The peak voltage $V_{transmitter}$ was 100 mV and therefore below the pacing threshold (4) to prevent unwanted myocardial stimulation at low frequencies (~1 kHz). The receiver voltage $V_{receiver}$ was amplified with a custom-made, battery-powered measurement amplifier and measured with a battery-driven oscilloscope (RTH1004, Rohde & Schwarz, Munich, Germany). The trials were approved by the Swiss

Federal Veterinary Office and performed in compliance with the Guide for the Care and Use of Laboratory Animals.

Leadless PMs are mainly surrounded by blood. Hence, the transfer function of porcine blood was measured in addition to the heart measurements. A container (100 ml volume) was filled with heparinized (1 ml/l) blood, freshly harvested from the slaughterhouse. The needle electrodes were placed with electrode distance $d_e$ = 10 mm and device distance $d_d$ = 25/50 mm. To achieve a different hematocrit, the blood was diluted with Ringer's solution. Hematocrit levels were determined immediately before the measurement by using the Hb 201 DM System (HemoCue, Ängelholm, Sweden).

In addition, in vitro measurements were performed on ventricular tissue samples (10 pieces, cut out approximately 65 × 30 × 10 mm), which allowed for the separate examination of the influence of electrode distance $d_e$ and penetration depth $d_p$. The needle electrodes were placed at a fixed device distance of 20 mm. Subsequently, the transfer function was measured at varying electrode distances ($d_e$ = 5/10 mm) and penetration depths ($d_p$ = 3/5 mm).

**PROTOTYPES.** The previously acquired impedance and transfer function results were used as the basis to develop prototypes of leadless PMs that feature dual-chamber pacing. For this functionality, the prototypes have to perform bidirectional communication; that is, every device has to be able to transmit and receive data. Intrabody communication was implemented using a suitable carrier frequency and modulation method. The devices are battery-powered by a USB power bank (PQI power 6000CV, PQI, Shenzhen, China). For prototyping purposes, they were not miniaturized, and an epicardial implantation site was intended.

The hardware concept of the prototypes is shown as a block diagram in Figure 3. The prototypes are built around a microcontroller development board (NUCLEO-F103RB, STMicroelectronics, Geneva, Switzerland). The settings, such as communication and pacing parameters, can be configured via the user interface. To send data, the signal generator generates a sinusoidal voltage with adjustable communication frequency $f_c$. This signal is pulse position modulated: the data are encoded as several pulses with defined time shifts. This technique allows the transmission of several bits of data per pulse. In fact, one pulse is a multiple of a period ($n_{\text{periods}}$) of the communication frequency $f_c$, which is the frequency with lowest signal attenuation by the tissue. The time required for sending one synchronization message is defined as $t_{\text{sync}}$. To receive data, the voltage measured at the electrodes is amplified with a differential amplifier, filtered, and digitized with the microcontroller's analog-to-digital converter to obtain the reconstructed data.

**DUAL-CHAMBER PACING.** To test the prototypes in vivo, a domestic pig (60 kg) was prepared as previously described. Electrode fixation plates were sutured on the RA, RV, and the left ventricle (LV) (Figure 4), and the needle electrodes were inserted. Before testing, the pacing impedance and pacing threshold were measured with a CareLink programmer (model 2090, Medtronic) via the inserted electrodes. Subsequently, the prototypes were connected to the electrodes and programmed to perform asynchronous leadless dual-chamber pacing at a higher rate than the pig's intrinsic heart rate. A 3-lead electrocardiogram (ECG) was recorded simultaneously (g.USBamp, g.tec medical engineering, Schiedlberg, Austria).

The verification of the communication reliability was assessed by 3 measures. First, the ventricular PM showed visual feedback upon reception of a synchronization message. In addition, ventricular pacing was verified by the altered ECG morphology (widening and different configuration of QRS complex) and visible pacing spikes in the ECG (atrial and ventricular).

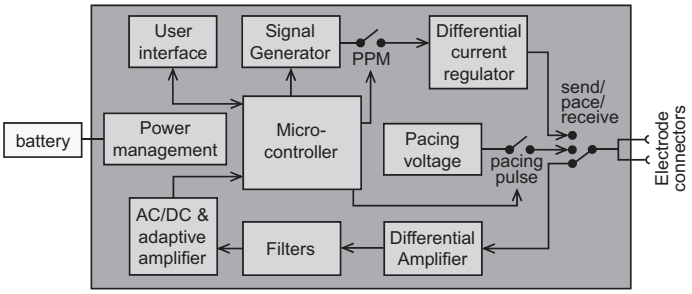
**ENERGY CONSUMPTION.** To evaluate the suitability of intrabody communication for leadless PMs, it is essential to consider the energy required by the communication. It can be divided into 2 parts. The first part is the electronic circuits' energy consumption (e.g., for signal amplification and processing, signal synthesis). In this proof-of-concept study, the developed prototypes have not been optimized in terms of energy efficiency. Therefore, emphasis is put on the second type of energy consumption, which is the transmitted energy. The transmitted energy is the energy that is applied to the tissue for communication ($E_{\text{sync}}$ is defined as the dissipated energy for one synchronization message). It is dependent on the amplitude of the applied signal, the tissue impedance $Z_e$, and on communication-specific parameters:

$$E_{\text{sync}} = \frac{\hat{I}^2 \cdot |Z_e|}{\sqrt{2}} \cdot n_{\text{pulses}} \cdot n_{\text{periods}} \cdot \frac{1}{f_c} \qquad \text{(Equation 2)}$$

## RESULTS

**IMPEDANCE AND TRANSFER FUNCTION MEASUREMENTS.** Measurements on 7 beating hearts (4 in vivo, 3 in a

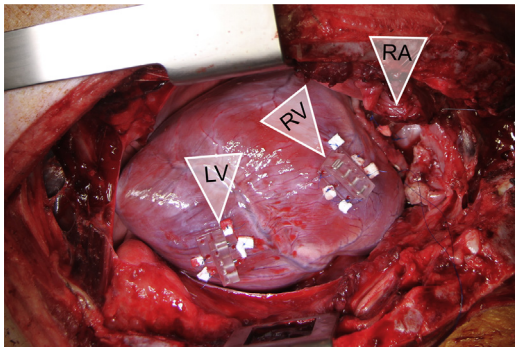
**FIGURE 3 Functional Block Diagram of the Pacemaker Prototypes**




To transmit, the data are pulse position modulated (PPM) and applied to the tissue via electrodes as alternating current. To receive data, the voltage measured at the electrodes is amplified, filtered, and rectified by an AC/DC converter and digitized by the microcontroller's analog-to-digital converter.

Langendorff setup) were performed with different electrode and device distances ($d_e$ = 7.5 to 15 mm; $d_d$ = 40 to 70 mm; and $d_p$ = 3 to 5 mm). During all communication experiments (~7 h in total), no interference with cardiac function was observed (i.e., no arrhythmias were induced). Figure 5A illustrates the 7 transfer functions between the RA and the RV. The signal attenuation is higher for lower frequencies (1 to 10 kHz). In the frequency range between 100 kHz and 1 MHz, a better signal transmission is obtained, and the attenuation remains approximately constant. Due to contraction of the heart and the resulting deformation of the myocardium, the attenuation varies during the heart cycle. This variation remained <5 dB.

**FIGURE 4 In Vivo Experiment Setup**




Top view of the heart of the in vivo dual-chamber pacing experiment. The positions of the electrode fixation plates are indicated by the triangles: right atrium (RA), right ventricle (RV), and left ventricle (LV).

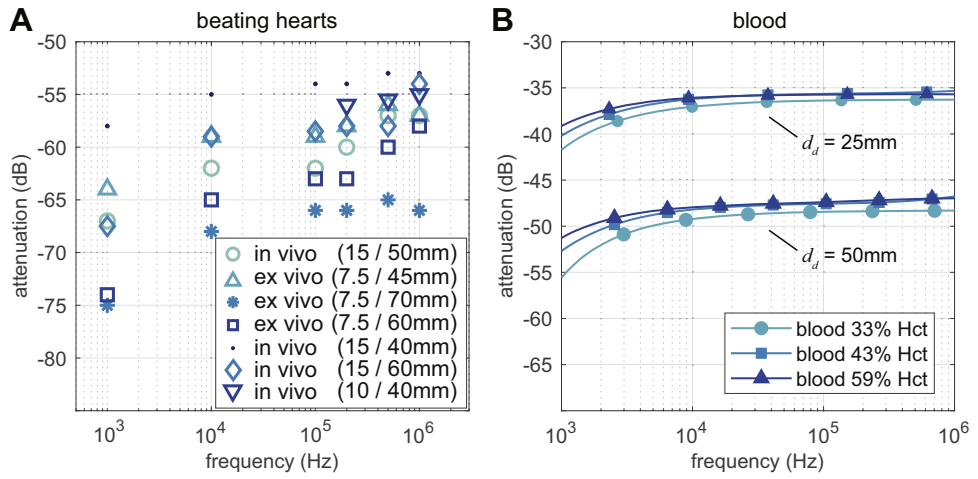
Figure 5B shows the transfer function in blood with various hematocrit levels at 2 different device distances (25 and 50 mm). Again, a better signal transmission is obtained for higher frequencies, whereas hematocrit does not affect the attenuation. However, the attenuation is increased upon a larger device distance. The influence of the other parameters was separately assessed in the myocardial tissue samples. Increasing the electrode distance $d_e$ from 5 to 10 mm resulted in a mean attenuation reduction of 11 dB (at $d_p$= 5 mm), and increasing the penetration depth $d_p$ (thus increasing the electrode contact area) from 3 to 5 mm reduced the attenuation by 3 dB (at $d_e$= 10 mm). This corresponds to a signal transmission improvement of 250% and 40%, respectively.

The impedance $Z_e$ is decreasing with higher frequencies. For the given dimensions, the measured impedance of heart tissue is in the range of 400 to 1,000 Ω for frequencies between 100 kHz and 1 MHz. The impedance is lower for smaller electrode distances and for higher electrode penetration depths (i.e., higher electrode contact surface area). Furthermore, it depends on the surrounding medium. The impedance of blood is generally lower compared with the myocardium, whereas the transfer function is comparable.

**PROTOTYPES.** The PM prototypes (Figure 6A) can communicate wirelessly via the heart by using intrabody communication. The data are pulse position modulated with an adjustable number of periods ($n_{\text{periods}}$) per pulse at a communication frequency $f_c$ of 100 kHz up to 1 MHz and adjustable current amplitude $\hat{I}$ (Figure 6B). The prototypes exchange a synchronization message at every heartbeat. The time $t_{\text{sync}}$ required for sending one synchronization message depends on communication-specific parameters and can range from 0.3 ms ($n_{\text{periods}}$ = 1; $f_c$ = 1 MHz) to 14 ms ($n_{\text{periods}}$ = 5; $f_c$ = 100 kHz), for example. For 1 synchronization message, 17 pulses are required to transmit 40 bits of data. The following information is implemented in this data package: preamble, message number, source (identification of transmitting PM), destination (identification of receiving PM), message type and length, pacing-related parameters (heart rate, atrioventricular pacing delay, and pacing activity), and cyclic redundancy check.

**DUAL-CHAMBER PACING.** The prototypes successfully performed leadless dual-chamber pacing in D00 mode during 3 in vivo trials. First, dual-chamber pacing on the RA and RV was tested. The atrial PM served as master device (atrial-based timing) and dictated the actual pacing rate (120 to 150 beats/min), the atrioventricular pacing delay, and pacing activity

**FIGURE 5 Signal Attenuation in the Heart and in Blood**



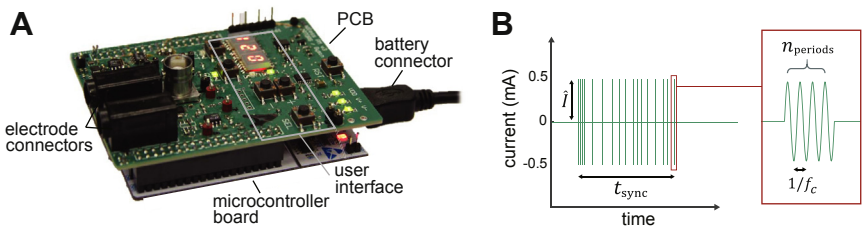

**(A)** Measured transfer function between the right atrium and the right ventricle. The dimensions in parentheses indicate the electrode distance and the device distance, respectively ($d_e/d_d$). **(B)** Transfer function of blood with different hematocrit (Hct) levels measured at 2 device distances.

(pacing on/off) to the receiving ventricular PM wirelessly. The atrioventricular delay was intentionally set below physiological levels to observe the ventricular excitation provoked dominantly by the pacing stimulus. Pacing was asynchronously started and stopped multiple times, with total pacing durations of ~20 min (>2,400 paced heartbeats) per in vivo experiment. Upon setup of communication, every single synchronization message was successfully received, and the communication did not cause any rhythm disturbances. The ECG sequence in **Figure 7** shows the onset of leadless dual-chamber pacing recorded: the atrial and ventricular pacing spikes are indicated by arrows.

The communication frequency $f_c$ was varied from 200 kHz to 1 MHz. Due to different attenuations in the various experiments, the transmitter current amplitude $\hat{I}$ was adapted to obtain a reliable communication (**Table 1**). This resulted in $E_{sync}$ of 0.3 to 1.5 μJ, which corresponds to an average power $P_{sync}$ of 0.6 to 3 μW for 120 beats/min pacing frequency. The duration $t_{sync}$ of sending 1 synchronization message was 0.9 to 7.2 ms, depending on communication settings.

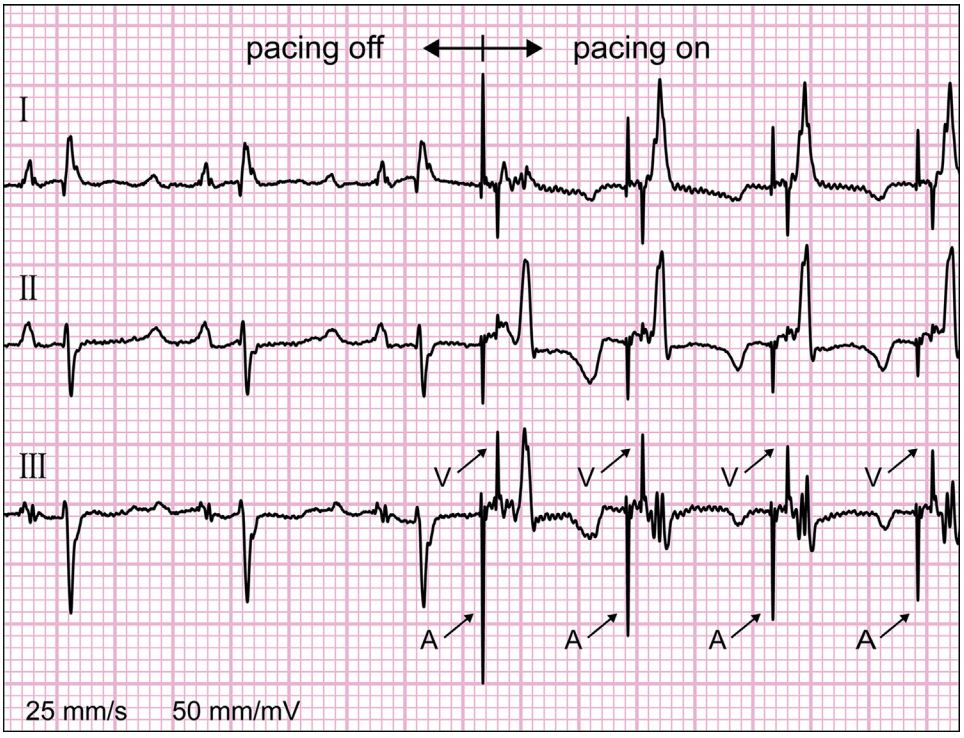
Dual-chamber pacing was also successfully tested in the LV and RV. Here, the left ventricular PM served as master device and pacing was performed with LV-RV pacing delays of 20 ms and 40 ms.

**FIGURE 6 Prototype and Representation of the Synchronization Message**




**(A)** Pacemaker prototype with electrode- and battery connectors and user interface. **(B)** Schematic representation of the pulse position–modulated synchronization message. The data are modulated as several short pulses, which have a communication frequency $f_c$ that is favorable for signal transmission. $f_c$ = communication frequency; PCB = printed circuit board.

**FIGURE 7** ECG Sequence of Leadless Dual-Chamber Pacing




Electrocardiogram (ECG) recorded during a dual-chamber test of the leadless pacemakers on the right atrium and right ventricle. The intrinsic heart rate was 98 beats/min. Dual-chamber pacing (D00) was performed at 120 beats/min and with 50 ms atrioventricular delay. The atrial (A) and ventricular (V) pacing spikes are indicated by the **arrows**.

## DISCUSSION

In this proof-of-concept study, we show, to the best of our knowledge, for the first time the feasibility of leadless cardiac dual-chamber pacing using intrabody communication. Intrabody communication has shown to be a suitable highly energy-efficient wireless communication method. This technology offers additional advantages such as the lack of an additional antenna (minimizing space requirements) and a short communication connection time.

**ENERGY CONSUMPTION.** The energy needed for PM synchronization strongly depends on communication-specific parameters. The transmitted power for communication was already low (0.6 to 3 μW) during the in vivo experiments. However, slightly changing some of the communication parameters can further decrease $P_{sync}$: using $n_{pulses} = 1$ and a communication frequency of 1 MHz would result in 12 nW of $P_{sync}$ considering a heart rate of 60 beats/min ($\hat{I} = 1$ mA). This approach corresponds to only ~0.1% of the power consumption of a

**TABLE 1** Communication Settings and Pacing Parameters During the 3 In Vivo Leadless Dual-Chamber Pacing Experiments

| Electrode Distance $d_e$ | Device Distance RA-RV $d_d$ (mm) | Pacing Threshold (V @ ms) | | | Pacing Impedance (Ω) | | | RA-RV Delay (ms) | Communication Frequency $f_c$ (kHz) | Current $\hat{I}$ (mA) |
|---|---|---|---|---|---|---|---|---|---|---|
| | | RA | RV | LV | RA | RV | LV | | | |
| 15 mm | 50 | 0.8 @ 1.5 | 1.0 @ 1.5 | 1.1 @ 1.5 | 1,046 | 1,244 | 1,153 | 50 | 200 | 1.0 |
| 10 mm | 40 | 3.4 @ 0.5 | 1.7 @ 0.5 | 1.5 @ 0.5 | 775 | 898 | 771 | 50 | 200, 500, 1,000 | 3.3 |
| 15 mm | 60 | 1.0 @ 1.0 | 1.5 @ 0.5 | 1.0 @ 0.5 | 726 | 1,234 | 975 | 50 | 500, 1,000 | 4.0 |

LV = left ventricle; RA = right atrium; RV = right ventricle.

contemporary leadless PM. Furthermore, by increasing the gain of the receiving amplifier, the transmitter current could be reduced.

$P_{sync}$ is the power applied to the tissue for communication and does not include the power consumption of the electronic circuits itself or the pacing stimulus. The prototypes' power consumption is relatively high (in the milliwatt range) due to the use of, for example, a microcontroller board, discrete off-the-shelf components, and the integration of a convenient user interface with visual feedback directly on the PM modules. However, the electronics' power consumption as well as the size could be reduced dramatically by the implementation of an integrated circuit, as done in commercial leadless PMs. Another strategy to reduce power consumption is the implementation of defined time slots for communication. Because receiving data requires most of the power, the devices should switch to sleep mode outside the communication time (e.g., during a blanking period), in which the power consumption is virtually zero.

**COMMUNICATION.** The transfer function measurements showed that the signal attenuation is higher for lower frequencies (1 to 10 kHz). This effect is mainly caused by the polarization impedance at the electrode-electrolyte interface, which is higher in this frequency range (17). In the frequency range between 100 kHz and 1 MHz, a better signal transmission is obtained, and the attenuation remains approximately constant. Hence, a communication frequency equal to or higher than ~100 kHz is favorable for intracardiac signal transmission.

The absolute signal attenuation varied between the experiments involving beating hearts, which was mainly caused by the different dimensions. In general, the attenuation is higher for larger device distances. However, it can be reduced by a larger electrode distance $d_e$ and deeper penetration depth $d_p$. Increasing $d_p$ leads to a larger electrode contact area, which is the actual reason for decreased signal attenuation.

The dependence of the attenuation on the relative spatial PM position also affects energy consumption. In general, a higher signal attenuation requires either a higher transmitter power or a more powerful amplifier on the receiving PM. In a real-world setting, these parameters could be dynamically adapted to optimize power consumption. Due to contraction of the heart and movement of the PMs, signal attenuation can even vary during a heartbeat. In the performed experiments, this variation was small (<5 dB), but it might be higher in different scenarios. Therefore, it is important to provide enough transmission budget to ensure a reliable communication.

The acute safety of the communication method has been shown by the lack of any unwanted arrhythmias. Due to the small energy content of a synchronization message (smaller than a typical pacing impulse), other adverse events such as tissue heating can also be excluded.

**IMPLICATIONS AND CLINICAL CONSIDERATIONS.** A crucial aspect of the presented wireless communication method is its ability to be integrated into contemporary leadless PMs. The dimensions and the design of these devices mainly follow the requirements of catheter-based implantation and the space constraints in the heart. The electrode design is optimized for cardiac pacing, but it would be desirable if the same electrodes could be simultaneously used for communication. The basic measurements have shown that higher electrode distances, as well as larger electrode surface areas, lead to lower signal attenuation. Fortunately, commercial leadless PMs have similar or even higher electrode distances $d_e$ (Nanostim: >10 mm; Micra: 18 mm) and larger electrode surface areas than those used in the presented experiments. The communication of the Nanostim is based on a similar idea as presented in the present study (7,18). However, the transmission characteristics to an external programmer differ significantly, and the restrictions on energy consumption are much lower (only temporary, short interrogations are performed, and the energy consumption of the programmer does not play a role). Moreover, our method allows for communication independent from the cardiac cycle.

Intrabody communication offers great advantages in terms of safety and hacking protection because the communication signal is confined to the human body (i.e., the body does not act as an antenna for the used communication frequency). Direct physical contact of a data transmitter with the body is required to establish a connection to the PMs. Thus, malicious change of the pacing parameters and leakage of sensitive information (e.g., PM settings) to surroundings is prevented. In addition, the use of low frequencies prevents hacking from conventional wireless transmitters (e.g., Bluetooth, ZigBee), which use a different frequency band.

This study presents a leadless dual-chamber PM. By implanting an additional leadless PM in the LV that communicates with the other 2 devices, the presented concept might also be extended to a leadless cardiac resynchronization therapy system.

**STUDY LIMITATIONS.** To simplify the in vivo experiments and to allow for better control of electrode placement, the needle electrodes were placed in an epicardial position. In real-life, leadless PMs are implanted in an endocardial position, where the cathode is in contact with myocardial tissue and the anode surrounded mainly by blood. However, the measurements in blood showed that blood has a lower impedance but offers similar signal attenuation as the myocardium. Therefore, it is reasonable to assume that the presented results are applicable to endocardial conditions as well.

Furthermore, the electrodes were arranged in a near-parallel configuration. However, different relative electrode angles may lead to different attenuations. The dependence of signal attenuation on geometric relations between the PMs is a general limitation of intrabody communication. The attenuation might be increased due to an altered device orientation, for example. Consequently, the transmitter current may need to be increased, which would result in a higher power consumption.

## CONCLUSIONS

Intrabody communication has shown to be a promising and energy-efficient wireless communication method for leadless dual-chamber PMs. The signal attenuation depends on the relative spatial position of the devices and can vary also during the heart cycle. By using suitable communication settings, the transmission power can be reduced drastically. In general, higher communication frequencies lead to better signal transmission as well as to a lower transmitted energy. The electrode design also plays an important role, whereby the electrodes of commercial leadless PMs seem to be suitable for intrabody communication.

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**ADDRESS FOR CORRESPONDENCE:** Mr. Lukas Bereuter, ARTORG Center, Murtenstrasse 50, 3008 Bern, Switzerland. E-mail: lukas.bereuter@artorg.unibe.ch.

## PERSPECTIVES

**COMPETENCY IN MEDICAL KNOWLEDGE:** Leadless PMs successfully overcome the lead-related limitations of conventional PMs, but they are thus far limited to single-chamber pacing. This study presented a proof of concept of a highly energy-efficient wireless communication method that may be used by multiple implanted leadless PMs for synchronization and may enable leadless dual-chamber pacing and leadless cardiac resynchronization therapy. In vitro and in vivo measurements provided a better understanding of the propagation of a communication signal in the heart and enabled the development of leadless dual-chamber PM prototypes that are optimized for intrabody communication in the heart.

**TRANSLATIONAL OUTLOOK:** At this time, the leadless dual-chamber PM prototypes have been successfully tested in 3 animal models. Further measurements will allow specification of a wider signal attenuation range and assessment of additional influential parameters such as the relative spatial position of the PMs. Future miniaturization of the prototypes will allow for long-term endocardial testing.

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**KEY WORDS** intrabody communication, leadless dual-chamber pacing, leadless pacemaker, low power, wireless communication